

**CHAPTER 5: 510(K) SUMMARY****MAR 19 2010****510(k) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

**1. Submitter of this pre-market notification:**

Haag-Streit AG  
Gartenstadtstrasse 10  
CH-3098 Koeniz / Switzerland

**Contact person:**

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This summary was prepared on November 16, 2009

**2. Trade names of the devices:**

- Slit Lamp BM 900
- Slit Lamp BQ 900
- Slit Lamp BP 900

**3. Common / usual name:**

AC-powered Slitlamp Biomicroscope

**4. Classification Information:**

Classification name: Biomicroscope, Slit-Lamp, AC-Powered  
CFR title: 21 CFR 886.1850  
Product code: HJO  
Device Class: Class II  
Classification Panel: Ophthalmic Device Panel

**5. Predicate Device:**

We claim substantial equivalence to the following device:

Manufacturer:	Haag-Streit AG
Device name:	Slit Lamp BC 900
510(k) Premarket Notification no.:	K982057
Classification name:	Biomicroscope, Slit-Lamp, AC-Powered
CFR title:	21 CFR 886.1850
Product code:	HJO
Device Class:	Class II
Classification Panel:	Ophthalmic Device Panel

**6. General Device Description:**

An AC-powered slitlamp biomicroscope is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

An AC-powered Slitlamp Biomicroscope is an AC-powered device that is a microscope intended for use in eye examination that projects into a patient's eye through a control diaphragm a thin, intense beam of light.

The slit lamp illumination is composed of the light source, the slit, collimation and imaging optics, and infrared and ultraviolet filters and a dielectric mirror. The slit lamps have the option to combine a background illumination together with the slit illumination.

The patient sits in front of the slit lamp with his chin in the chin rest and his forehead against the forehead band. The chin rest is adjusted in height until the eyes of the patient are level with the black mark of the headrest column. The light is switched on and the brightness is controlled with a knob on the power supply and with a 10% grey filter. With the control lever the instrument can be moved back- and forward until the slit appears in focus on the cornea. The image can be observed through the microscope. Various magnifications can be selected on the microscope. For different observations the slit width can be changed, the slit can be tilted horizontally and vertically, and the angle between the illumination unit and the microscope can also be varied horizontally.

**7. Indication for use**

An AC-powered slitlamp biomicroscope is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

### **8. Comparison with predicate device**

The slit lamps BM 900, BQ 900 and BP 900 are substantially equivalent to the predicate device BC 900, because they use similar technology and perform similar functions to provide the physician with the necessary information to make a diagnosis.

Major different technological characteristics are as follows:

	<b>Predicate Device Haag-Streit Slit Lamp BC 900</b>	<b>Haag-Streit Slit Lamps BM 900 / BQ 900 / BP 900</b>	<b>Description of differences and discussion</b>
<b>Brightness Controls</b>	<p><b><u>With Power Supply LC-SLT and Halogen Bulb:</u></b> Variable control by potentiometer: Maximum brightness: Position 1: approx. 300'000 Lux</p>	<p><b><u>For BM 900 and BQ 900:</u></b>   <b><u>With Power Supply PS-A and Tungsten Bulb:</u></b> Rotating switch with 3 steps: Maximum brightness: Position 2: approx. 600'000 Lux   <b><u>With Power Supply PS-A and Halogen Bulb:</u></b> Rotating switch with 3 steps: Maximum brightness: Position 2: approx. 370'000 Lux   <b><u>With Power Supply PS-AV and Tungsten Bulb:</u></b> Variable control by potentiometer: Maximum brightness: Position 2: approx. 600'000 Lux   <b><u>With Power Supply PS-AV and Halogen Bulb:</u></b> Variable control by potentiometer: Maximum brightness: Position 2: approx. 370'000 Lux   <b><u>With Power Supply PS-LED and LED:</u></b> Variable control by potentiometer: Maximum brightness: Position 10: approx. 450'000 Lux   <b><u>Additional Fill Illumination FI 01f:</u></b> Variable control by potentiometer: Maximum brightness: Position 10: approx. 15'000 Lux   <b><u>Additional Fill Illumination FI 01p:</u></b> Variable control by potentiometer: Maximum brightness: Position 10: approx. 30'000 Lux</p>	<p>The brightness controls are either by a variable, continuous potentiometer, by a rotating switch with fixed positions or by a push button.</p> <p>The maximum brightness of the slit lamps differs.</p> <p>The differences in brightness controls are not significant. They allow the user to select a convenient brightness to achieve optimum results.</p> <p>The maximum brightness is significantly different. The predicate device BC 900 has a maximum brightness of approx. 300'000 Lux, whereas the slit lamps BM 900, BQ 900 and BP 900 can have approx. 600'000 Lux with the tungsten bulb and approx. 370'000 Lux with the halogen bulb. As all slit lamps conform to the relevant standard ISO 10939, there are no new issues of safety and effectiveness.</p>

	Predicate Device Haag-Streit Slit Lamp BC 900	Haag-Streit Slit Lamps BM 900 / BQ 900 / BP 900	Description of differences and discussion
Brightness Controls		<p><b>For BP 900:</b></p> <p>With <u>Power Supply PS-B and Tungsten Bulb:</u> Push-button control in 3 steps: Maximum brightness: Level 2: approx. 600'000 Lux</p> <p>With <u>Power Supply PS-B and Halogen Bulb:</u> Push-button control in 3 steps: Maximum brightness: Level 2: approx. 370'000 Lux</p> <p>With <u>Power Supply PS-LED and LED:</u> Variable control by potentiometer: Maximum brightness: Position 10: approx. 450'000 Lux</p> <p><u>Additional Fill Illumination FI 01f:</u> Variable control by potentiometer: Maximum brightness: Position 10: approx. 15'000 Lux</p> <p><u>Additional Fill Illumination FI 01p:</u> Variable control by potentiometer: Maximum brightness: Position 10: approx. 30'000 Lux</p>	See above
Slit image width	0 - 14 mm continuous	0 - 8 mm continuous	<p>The differences are not significant. The predicate device BC 900 has a larger slit width, because when fitting contact lenses it is necessary to illuminate the whole cornea up to the sclera.</p> <p>The slit lamps BM 900, BQ 900 and BP 900 are mainly used to examine the inner parts of the eye. For this a very narrow slit width is needed, usually less than 1 mm. For this reason it is not necessary for these slit lamps to have a slit width wider than 8 mm.</p> <p>There are no new issues of safety and effectiveness.</p>

	<b>Predicate Device Haag-Streit Slit Lamp BC 900</b>	<b>Haag-Streit Slit Lamps BM 900 / BQ 900 / BP 900</b>	<b>Description of differences and discussion</b>
Slit image length	1 - 14 mm continuous	1 - 8 mm continuous	<p>The differences are not significant.</p> <p>As the illumination field is defined by a circular aperture, the slit length can not be larger than the slit width.</p> <p>For slit lamps BM 900, BQ 900 and BP 900 a slit length of 8 mm is sufficient as the Iris usually has a diameter of maximum 6 mm.</p> <p>There are no new issues of safety and effectiveness.</p>
Illumination field diameter	14 mm	Ø 8 / 5 / 3 / 2 / 1 / 0.2mm	<p>The differences are not significant.</p> <p>The slit lamp BC 900 has the possibility to continuously adjust the illumination field diameter from 1mm to 14mm, the slit lamps BM 900, BQ 900 and BP 900 can adjust from 1mm to 8mm. Additionally the slit lamps BM 900, BQ 900 and BP 900 can chose some fixed diameters for user's convenience.</p> <p>As described further up the difference in field diameter is due to the intended use.</p> <p>There are no new issues of safety and effectiveness.</p>

	Predicate Device Haag-Streit Slit Lamp BC 900	Haag-Streit Slit Lamps BM 900 / BQ 900 / BP 900	Description of differences and discussion
Radial movement of the slit light illumination relative to the microscope axis	horizontal $\pm 90^\circ$	horizontal $\pm 90^\circ$ , vertical 0 - $20^\circ$	<p>This difference is not significant.</p> <p>When examining the inner parts of the eye sometimes it may be advantageous to use a horizontal slit for a clear view. In order to have a view to this examination plane it is necessary to be able to move the slit light illumination also in a vertical axis, which is possible with the slit lamps BM 900, BQ 900 and BP 900.</p> <p>This feature is not needed for the slit lamp BC 900.</p> <p>There are no new issues of safety and effectiveness.</p>
Light sources	1. Halogen Bulb 12V / 2.5A	1. Tungsten Bulb 6V / 4.5A 2. Halogen Bulb 7.5V / 38W 3. LED Illumination LI 900	<p>The difference in light source is significant. Predicate device BC 900 has a 12V 2.5A halogen bulb, whereas the slit lamps BM 900, BQ 900 and BP 900 can have a 7.5V 38W halogen bulb, a 6V 4.5A tungsten bulb or the 24VDC 1A LED.</p> <p>As all slit lamps conform to the relevant standard ISO 10939, there are no new issues of safety and effectiveness.</p>

### **9. Performance, Safety and EMC Data**

The slit lamps BM 900 and BP 900 illumination units and electrical systems are identical to the BQ 900 illumination unit and electrical system. Therefore all measurements and tests were done with the BQ 900 and have not been repeated for the BM 900 and BP 900.

The slit lamp BQ 900 was tested according to ISO 15004-2:2007 and ISO 10939:2007 for radiation hazards, to IEC 60601-1 for electrical safety and to IEC 60601-1-2 for electromagnetic compatibility. In all tests the slit lamp was in compliance with these FDA-recognized standards.

**10. Conclusions**

In accordance to 21 CFR 807.92(d) and based on the technical characteristics and the results of the performance tests we conclude that the slit lamps BM 900, BQ 900 and BP 900 are substantially equivalent and as safe and effective as the predicate device slit lamp BC 900.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

MAR 19 2010

HAAG-STREIT AG  
c/o Mr. Stefan Preiss  
TUV SUD America Inc.  
1775 Old Highway 8 NW  
New Brighton, MN 55112

Re: K100202

Trade Name: Slit Lamp BM 900, BQ 900, BP 900  
Regulation Number: 21 CFR 886.1850  
Regulation Name: AC-powered slitlamp biomicroscope  
Regulatory Class: Class II  
Product Code: HJO  
Dated: March 2, 2010  
Received: March 4, 2010

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

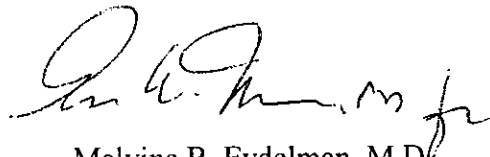
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Malvina B. Eydelman".

Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic, Neurological and  
Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Form

510(k) Number (if known): K 100202

Device Name: Slit Lamp BM 900 / Slit Lamp BQ 900 / Slit Lamp BP 900


Indications for Use:

An AC-powered slitlamp biomicroscope is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

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